This Listing of Claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS

Claim 1 (previously presented): A purified, large-scale preparation comprising at least 200 grams of tissue factor pathway inhibitor (TFPI) or TFPI analog molecules, wherein less than 12% of the TFPI or TFPI analog molecules are modified species, wherein the modified species include one or more of the following:

an oxidized TFPI or TFPI analog molecule, as detected by reverse phase chromatography;

a carbamylated TFPI or TFPI analog molecule, as detected by cation exchange chromatography;

a deamidated TFPI or TFPI analog molecule, as detected through indirect measurement of isoaspartic acid;

a TFPI or TFPI analog molecule that comprises a cysteine adduct, as determined by amino acid analysis;

aggregated TFPI or TFPI analog molecules, as detected by size exclusion chromatography; and

a misfolded TFPI or TFPI analog molecule, as detected by non-denaturing SDS-polyacrylamide gel electrophoresis.

Claim 2 (currently amended): The purified preparation of ~~claim 1~~claim 1, wherein less than about 9% of the TFPI or TFPI analog molecules are oxidized.

Claim 3 (currently amended): The purified preparation of ~~claim 1~~claim 1, wherein less than about 3% of the TFPI or TFPI analog molecules are carbamylated.

Claim 4 (currently amended): The purified preparation of ~~claim 1~~claim 1, wherein less than about 9% of the TFPI or TFPI analog molecules are deamidated.

Claim 5 (currently amended): The purified preparation of ~~claim 1~~claim 1, wherein less than about 2% of the TFPI or TFPI analog molecules comprise a cysteine adduct.

Claim 6 (currently amended): The purified preparation of ~~claim 1~~claim 1, wherein less than about 3% of the TFPI or TFPI analog molecules are aggregated.

Claim 7 (currently amended): The purified preparation of ~~claim 1~~claim 1, wherein less than about 3% of the TFPI or TFPI analog molecules are misfolded.

Claim 8 (currently amended): The purified preparation of ~~claim 1~~claim 1, wherein members of the plurality of TFPI molecules have the amino acid sequence shown in SEQ ID NO:1.

Claim 9 (currently amended): The purified preparation of ~~claim 1~~claim 1, wherein the TFPI analog molecules are ala-TFPI molecules.

Claim 10 (previously presented): A large-scale pharmaceutical formulation comprising at least 200 grams of tissue factor pathway inhibitor (TFPI) or TFPI analog molecules, wherein less than

12% of the TFPI or TFPI analog molecules are modified species wherein the modified species include one or more of the following:

an oxidized TFPI or TFPI analog molecule, as detected by reverse phase chromatography;

a carbamylated TFPI or TFPI analog molecule, as detected by cation exchange chromatography;

a deamidated TFPI or TFPI analog molecule, as detected through indirect measurement of isoaspartic acid;

a TFPI or TFPI analog molecule that comprises a cysteine adduct, as determined by amino acid analysis;

aggregated TFPI or TFPI analog molecules, as detected by size exclusion chromatography; and

a misfolded TFPI or TFPI analog molecule, as detected by non-denaturing SDS-polyacrylamide gel electrophoresis.

Claim 11 (currently amended): The pharmaceutical formulation of ~~claim 10~~ claim 10, wherein less than about 3% of the TFPI or TFPI analog molecules are oxidized.

Claim 12 (currently amended): The pharmaceutical formulation of ~~claim 10~~ claim 10, wherein less than about 3% of the TFPI or TFPI analog molecules are carbamylated.

Claim 13 (currently amended): The pharmaceutical formulation of ~~claim 10~~ claim 10, wherein less than about 9% of the TFPI or TFPI analog molecules are deamidated.

Claim 14 (currently amended): The pharmaceutical formulation of ~~claim 10~~ claim 10, wherein less than about 3% of the TFPI or TFPI analog molecules comprise a cysteine adduct.

Claim 15 (currently amended): The pharmaceutical formulation of ~~claim 10~~ claim 10, wherein less than about 3% of the TFPI or TFPI analog molecules are aggregated.

Claim 16 (currently amended): The pharmaceutical formulation of ~~claim 10~~ claim 10, wherein less than about 3% of the TFPI or TFPI analog molecules are misfolded.

Claim 17 (currently amended): The pharmaceutical formulation of ~~claim 10~~ claim 10, wherein members of the plurality of TFPI or TFPI analog molecules are TFPI molecules that have the amino acid sequence shown in SEQ ID NO:1.

Claim 18 (currently amended): The pharmaceutical formulation of ~~claim 10~~ claim 10, wherein members of the plurality of TFPI or TFPI analog molecules are ala-TFPI molecules.

Claim 19 (previously presented): A large-scale pharmaceutical formulation comprising:

at least 200 grams of tissue factor pathway inhibitor molecules having an additional amino terminal alanine residue (ala-TFPI), wherein less than 12% of the TFPI or TFPI analog molecules are modified species, wherein the modified species include one or more of the following:

an oxidized ala-TFPI molecule, as detected by reverse phase chromatography;

a carbamylated ala-TFPI molecule, as detected by cation exchange chromatography;

a deamidated ala-TFPI molecule, as detected through indirect measurement of isoaspartic acid;

an ala-TFPI molecule that comprises a cysteine adduct, as determined by amino acid analysis;

aggregated TFPI or TFPI analog molecules, as detected by size exclusion chromatography; and

a misfolded ala-TFPI molecule, as detected by non-denaturing SDS-polyacrylamide gel electrophoresis,

wherein the pharmaceutical formulation comprises 20 mM sodium citrate, 300 mM L-arginine, and 5 mM methionine, pH 5.5.

Claim 20 (withdrawn): A method of producing the purified, large-scale preparation of claim 1, comprising the steps of:

(1) expressing TFPI or a TFPI analog in a rifampicin-resistant *E. coli* host cell, wherein the TFPI or the TFPI analog is encoded on a plasmid comprising the following elements:

(a) a transcription promoter;

(b) a ribosome binding site adjacent to the reclac transcription promoter;

(c) a nucleotide coding sequence that encodes the TFPI or the TFPI analog adjacent to the ribosome binding site;

(d) a transcription terminator adjacent to the nucleotide coding sequence;

(e) a replicon;

(f) an antibiotic resistance gene; and

(g) a gene encoding an N-terminal methionine-removing enzyme;

(2) isolating inclusion bodies containing the TFPI or the TFPI analog from the *E. coli* host cell;

(3) isolating the TFPI or the TFPI analog from the inclusion bodies to obtain isolated TFPI or TFPI analog;

(4) refolding the isolated TFPI or TFPI analog to form refolded TFPI or TFPI analog;

(5) purifying the refolded TFPI or TFPI analog by SP-Sepharose fast flow chromatography in the presence of Mg^{++} to form a first preparation of purified TFPI or TFPI analog;

(6) concentrating the first preparation of purified TFPI or TFPI analog to form a first concentrated preparation of purified TFPI or TFPI analog;

(7) purifying the first concentrated preparation of purified TFPI or TFPI analog by Q-Sepharose HP chromatography to form a second preparation of purified TFPI or TFPI analog;

(8) purifying the second preparation of purified TFPI or TFPI analog by butyl HIC chromatography to form a third preparation of purified TFPI or TFPI analog;

(9) purifying the third preparation of purified TFPI or TFPI analog by SP-Sepharose HP chromatography to form a fourth preparation of purified TFPI or TFPI analog;

(10) concentrating the fourth preparation of purified TFPI or TFPI analog to form a second concentrated preparation of purified TFPI or TFPI analog molecules, wherein less than about 12% of the TFPI or TFPI analog molecules are modified TFPI or TFPI analog molecules.

Claim 21 (withdrawn): The method of claim 20 wherein the transcription promoter is a reclac promoter.

Claim 22 (withdrawn): The method of claim 20 wherein the ribosome binding site is the ribosome binding site from gene 10 of bacteriophage T7.

Claim 23 (withdrawn): The method of claim 20 wherein the nucleotide coding sequence encodes ala-TFPI.

Claim 24 (withdrawn): The method of claim 23 wherein the nucleotide coding sequence is SEQ ID NO:44.

Claim 25 (withdrawn): The method of claim 20 wherein the transcription terminator comprises the nucleotide sequence shown in SEQ ID NO:42.

Claim 26 (withdrawn): The method of claim 20 wherein the replicon comprises a pBR322 origin of replication.

Claim 27 (withdrawn): The method of claim 20 wherein the replicon comprises a rop copy number control gene from pBR322.

Claim 28 (withdrawn): The method of claim 20 wherein the antibiotic resistance gene is streptomycin adenyltransferase.

Claim 29 (withdrawn): The method of claim 20 wherein the N-terminal methionine-removing enzyme is *E. coli* methionine aminopeptidase.

Claim 30 (withdrawn): The method of claim 20 wherein the *E. coli* host cell is MON210 (ATCC Accession No. PTA-5564).

Claim 31 (withdrawn): A method of purifying tissue factor pathway inhibitor (TFPI) or TFPI analog molecules to provide the purified, large-scale preparation of claim 1, comprising the steps of:

(1) purifying recombinantly produced TFPI or TFPI analog molecules by SP-Sepharose fast flow chromatography to form a first preparation of purified TFPI or TFPI analog;

(2) concentrating the first preparation of purified TFPI or TFPI analog to form a first concentrated preparation of purified TFPI or TFPI analog;

(3) purifying the first concentrated preparation of purified TFPI or TFPI analog by Q-Sepharose HP chromatography to form a second preparation of purified TFPI or TFPI analog;

(4) purifying the second preparation of purified TFPI or TFPI analog by butyl HIC chromatography to form a third preparation of purified TFPI or TFPI analog;

(5) purifying the third preparation of purified TFPI or TFPI analog by SP-Sepharose HP chromatography to form a fourth preparation of purified TFPI or TFPI analog;

(6) concentrating the fourth preparation of purified TFPI or TFPI analog to form a second concentrated preparation of purified TFPI or TFPI analog molecules, wherein less than about 12% of the TFPI or TFPI analog molecules are modified TFPI or TFPI analog molecules.

Claim 32 (withdrawn): The method of claim 31 wherein the SP-Sepharose fast flow chromatography is performed in the presence of Mg^{++}.

Claim 33 (withdrawn): The method of claim 31 wherein the TFPI or TFPI analog molecules are produced in yeast cells.

Claim 34 (withdrawn): The method of claim 31 wherein the TFPI or TFPI analog molecules are produced in mammalian cells.

Claim 35 (withdrawn): The method of claim 34 wherein the mammalian cells are CHO cells.

Claim 36 (withdrawn): The method of claim 34 wherein the mammalian cells are HepG2 cells.

Claim 37 (withdrawn): The method of claim 34 wherein the mammalian cells are Chang liver cells.

Claim 38 (withdrawn): The method of claim 34 wherein the mammalian cells are SK hepatoma cells.

Claim 39 (withdrawn): A method of expressing tissue factor pathway inhibitor (TFPI) or TFPI analog to provide the purified, large-scale preparation of claim 1, comprising:

(1) culturing a rifampicin-resistant *E. coli* host cell in a fermentation medium, wherein the *E. coli* host cell comprises a plasmid having the following elements:

(a) a transcription promoter;

(b) a ribosome binding site adjacent to the reclac transcription promoter;

(c) a nucleotide coding sequence that encodes TFPI or TFPI analog adjacent to the ribosome binding site;

(d) a transcription terminator adjacent to the nucleotide coding sequence;

(e) a replicon;

(f) an antibiotic resistance gene; and

(g) a gene encoding an N-terminal methionine-removing enzyme;

wherein one liter of the fermentation medium comprises 41 g dextrose, 2.5 g $(NH_4)_2SO_4$, 4.0 g sodium polyphosphate, 7.0 g K_2SO_4, 1.63 g $MgSO_4 \cdot 7H_2O$, 2.0 g methionine, 2.0 g glycerol, 0.5 mg H_3BO_4, 0.5 g cobalt chloride, 0.13 g $CuSO_4 \cdot 6H_2O$, 54.0 g $FeCl_3 \cdot 6H_2O$, 11.0 g $MnSO_4 \cdot H_2O$, 0.5 g $Na_2MoO_4 \cdot 2H_2O$, 0.02 $NaSeO_3$, 22.0 g $ZnSO_4 \cdot 7H_2O$, 0.01 ml concentrated H_2SO_4, and 0.55 ml UCON antifoam.

Claim 40 (withdrawn): The method of claim 39 wherein the transcription promoter is a reclac promoter.

Claim 41 (withdrawn): The method of claim 39 wherein the ribosome binding site is the ribosome binding site from gene 10 of bacteriophage T7.

Claim 42 (withdrawn): The method of claim 39 wherein the nucleotide coding sequence encodes ala-TFPI.

Claim 43 (withdrawn): The method of claim 42 wherein the nucleotide coding sequence is SEQ ID NO:44.

Claim 44 (withdrawn): The method of claim 39 wherein the transcription terminator comprises the nucleotide sequence shown in SEQ ID NO:42.

Claim 45 (withdrawn): The method of claim 39 wherein the replicon comprises a pBR322 origin of replication.

Claim 46 (withdrawn): The method of claim 39 wherein the replicon comprises a rop copy number control gene from pBR322.

Claim 47 (withdrawn): The method of claim 39 wherein the antibiotic resistance gene is streptomycin adenyltransferase.

Claim 48 (withdrawn): The method of claim 39 wherein the N-terminal methionine-removing enzyme is *E. coli* methionine aminopeptidase.

Claim 49 (withdrawn): The method of claim 39 wherein the *E. coli* host cell is MON210 (ATCC Accession No. PTA-5564).

Claim 50 (previously presented): The purified, large-scale preparation of claim 1 comprising 200 grams to 2.4 kilograms of tissue factor pathway inhibitor (TFPI) or TFPI analog.

Claim 51 (previously presented): The purified, large-scale preparation of claim 50 comprising 200-300 grams of tissue factor pathway inhibitor (TFPI) or TFPI analog.

Claim 52 (previously presented): The purified, large-scale preparation of claim 50 comprising 400-600 grams of tissue factor pathway inhibitor (TFPI) or TFPI analog.

Claim 53 (previously presented): The purified, large-scale preparation of claim 50 comprising 600-900 grams of tissue factor pathway inhibitor (TFPI) or TFPI analog.

Claim 54 (previously presented): The purified, large-scale preparation of claim 50 comprising 800-1200 grams of tissue factor pathway inhibitor (TFPI) or TFPI analog.

Claim 55 (previously presented): The purified, large-scale preparation of claim 1, wherein indirect measurement of isoaspartic acid comprises analyzing a byproduct S-adenosyl-homocysteine (SAH) by RP-HPLC, wherein the byproduct is generated from the transfer of a methyl group from S-adenosyl-L-methionine (SAM) to isoaspartic acid, catalyzed by Protein Isoaspartyl Methyl Transferase (PIMT).

Claim 56 (currently amended): The large-scale pharmaceutical formulation ~~purified, large-scale preparation~~ of claim 10, wherein indirect measurement of isoaspartic acid comprises analyzing a byproduct S-adenosyl-homocysteine (SAH) by RP-HPLC, wherein the byproduct is generated from the transfer of a methyl group from S-adenosyl-L-methionine (SAM) to isoaspartic acid, catalyzed by Protein Isoaspartyl Methyl Transferase (PIMT).

Claim 57 (currently amended): The large-scale pharmaceutical formulation ~~purified, large-scale preparation~~ of claim 19, wherein indirect measurement of isoaspartic acid comprises analyzing a byproduct S-adenosyl-homocysteine (SAH) by RP-HPLC, wherein the byproduct is generated from the transfer of a methyl group from S-adenosyl-L-methionine (SAM) to isoaspartic acid, catalyzed by Protein Isoaspartyl Methyl Transferase (PIMT).